

REMARKS

Claim Amendment

Claim 2 has been amended to further clarify the feature of being self-crosslinkable in situ shortly after injection. Claim 9 depends directly from Claim 2. The following remarks in response to the art rejections are respectfully provided to clarify the subject matter claimed by the present invention and to patentably distinguish the claims from the cited references.

Art Rejections

Claims 2 and 9 were rejected under 35 U.S.C. 103(a) as being unpatentable over Jo et al (US 2002/0028189), herein "Jo," as evidenced by Xie et al (Experimental investigation on the reliability of routine SEC-MALLS for the determination of absolute molecular weights in the oligomeric range, Polymer, vol 43, issue 14, 2002, pp 3973-3977), herein "Xie."

Jo does not teach a self-crosslinkable copolymer as claimed in Claim 2 of the present invention. Applicants therefore submit that the invention is not obvious under Jo for the following reasons.

Jo fails to disclose a self-crosslinkable copolymer consisting essentially of caprolactone units and fumarate units with all of the limitations recited in Claim 2. Jo describes an oligomer OPF that must be crosslinked using radical polymerization in the presence of either a chemical or photo initiator in the presence of a crosslinking agent such as polyethylene glycol diacrylate as disclosed in Jo at paragraph [0037].

In contrast to Jo, Applicants' invention of self-crosslinkable PCLF has carbon-carbon double bonds that can be used for in situ self-crosslinking, without additional crosslinking agents. The fumaryl chloride is copolymerized with biodegradable poly(caprolactone) macromer that has a flexible backbone such that the resulting copolymer may be cross-linked in the absence of a crosslinking agent. An example of a crosslinking agent is polyethylene glycol diacrylate, among others. Polyethylene glycol diacrylate is required to crosslink OPF (typically 50 weight % crosslinking agent compared to OPF is used) in addition to the radical initiator shown in Jo. PCLF needs only the radical initiator to crosslink PCLF.

The Examiner's position is that the "absolute MWD values" of the Application and Jo's polymers are equal, since the "same monomers" are used. Regarding the other claim limitations, claiming melting and hardening points range, the Examiner asserts that the same physical properties are expected since the structure of Jo's and Applicant's polymers is identical.

Applicants submit that the Examiner means absolute molecular weight, not MWD. Applicants also disagree with the Examiner's conclusion about the monomers being the same. The monomers are not the same, polycaprolactone and polyethylene glycol are different. They make up the bulk of the material, usually around 90% or so of the resulting polymers. Essentially they are polymers composed of polyethylene glycol or polycaprolactone which are different than Jo's polymers.

Also Xie uses a different polymer than either polycaprolactone or polyethylene glycol and the discrepancies in absolute molecular weight for that polymer cannot be directly applied to the polymers used in either Applicants' invention or the Jo patent.

Jo's OPF and Applicants' PCLF have significantly different physical and mechanical properties. OPF as shown in the publication (a copy is enclosed for the Examiner): Temenoff, Effect of poly(ethylene glycol) molecular weight on tensile and swelling properties of oligo(poly(ethylene glycol) fumarate) hydrogels for cartilage tissue engineering, J Biomed Mater Res 59: 429–437, 2002, John Wiley & Sons, Inc. (herein "Temenoff"), has a tensile modulus as high as 90 kPa (see page 433). In contrast, PCLF as reported by Wang, et al., Photo-crosslinked poly(ϵ -caprolactone fumarate) networks: Roles of crystallinity and crosslinking density in determining mechanical properties, Polymer 49 (2008) 5692–5699, Elsevier (a copy is enclosed for the Examiner) has a tensile modulus as high as about 140 MPa (or 140,000 kPa) (see page 5698). Thus, the tensile modulus of Applicants' material is over 1000 times greater than that of the OPF disclosed by Jo. This multiple order of magnitude difference provides advantages in Applicants' invention.

Another important fundamental difference between the Jo material and that of Applicants' invention is that Jo's OPF material is a hydrogel. Consequently, it swells significantly in water or in a physiological environment, whereas PCLF does not. This difference is shown in Temenoff and Wang.

Claim 9 was rejected under 35 USC 103(a) as being unpatentable over Jo. Applicants maintain that Claim 2 is patentable for the above reasons, so Claim 9 which depends from Claim 2 is also patentable.

Conclusion

A fee of \$555 for a three-month extension of time (37 CFR 1.17(a)(3)) is believed to be needed for this amendment. A form PTO 2038 for credit card payment of the fee is enclosed along with a PTO/SB/22 Petition for Extension of Time under 37 CFR 1.136(a). If any refund is due, please submit a check to the undersigned.

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